IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

BETTY PHELPS and DELBERT PHELPS,

Plaintiffs,

v.

WYETH, INC.; SCHWARZ PHARMA, INC.; PLIVA USA, INC.; NORTHSTAR RX, LLC; and ALAVEN PHARMACEUTICAL, LLC.,

Defendants.

Civ. No. 6:09-cv-06168 TC

OPINION AND ORDER

AIKEN, Chief Judge:

Plaintiffs bring this action alleging Betty Phelps was injured after ingesting a generic version of the prescription drug metoclopramide manufactured by Pliva from 2004 through 2007. Specifically, plaintiffs alleged that Pliva was negligent by failing to adequately warn Mrs. Phelps of the dangers of using metoclopramide and by failing to update its product label in 2003 and 2004 to match the warning on the brand-name product. In 2012,

Judge Coffin found that plaintiffs' failure to adequately warn claim against Pliva was preempted by PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), and recommended that the undersigned dismiss that claim. (Doc. 260). In April 2012, I adopted Judge Coffin's findings and recommendations and dismissed plaintiffs' failure to warn claim. Remaining is plaintiff's failure to update claim against Pliva. (Doc. 296).

In July 2012, Pliva filed the instant motion for summary judgment on plaintiffs' failure to update claim, arguing that plaintiffs' claim is preempted by federal law and not recognized under Oregon law. (Doc. 301). After oral argument and briefing on the issue, Judge Coffin issued a Findings and Recommendation (F&R) that I deny Pliva's motion for summary judgment. (Doc. 344). Pliva objected to the F&R. (Doc. 347). For the reasons stated below, I adopt Judge Coffin's F&R and deny Pliva's motion for summary judgment.

I. STANDARDS

When a party objects to a magistrate judge's F&R regarding a dispositive motion, the district court must make a *de novo* determination of that portion of the magistrate judge's report. Fed. R. Civ. P. 72(b)(3); see 28 U.S.C. § 636(b)(1)(c); McDonnell Douglas Corp. v. Commodore Bus. Machs., Inc., 656 F.2d 1309, 1313 (9th Cir. 1981). For non-dispositive motions, the magistrate's findings are reviewed for clear error. Fed. R. Civ. P. 72(a); Henry

v. Gill Indus., Inc., 983 F.2d 943, 946 (9th Cir. 1993). Defendant filed timely objections to Judge Coffin's findings. I give *de novo* review of the defendant's objections to the F&R regarding defendant's motion for summary judgment.

Summary judgment is appropriate if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In order to grant summary judgment, there must be no genuine issue of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). The movant has the initial burden of establishing that no genuine issue of material fact exists or that a material fact essential to the nonmovant's claim is missing. Celotex Corp. v. Catrett, 477 U.S. 317, 322-24 (1986). Summary judgment is also appropriate where federal law preempts a plaintiff's state law claims. See e.g., Bank of Am. v. City & Cnty. of S.F., 309 F.3d 551, 556 (9th Cir. 2002).

Once the movant has met its burden, the burden shifts to the nonmovant to produce specific evidence to establish a genuine issue of material fact or to establish the existence of all facts material to the claim. Celotex, 477 U.S. at 322-24; see also Bhan v. NME Hosp., Inc., 929 F.2d 1404, 1409 (9th Cir. 1991); Nissan Fire & Marine Ins. Co., Ltd., v. Fritz Cos., Inc., 210 F.3d 1099, 1105 (9th Cir. 2000).

II. BACKGROUND

The following facts are undisputed. Metoclopramide is a prescription drug available in both name-brand and generic forms. Defendant Pliva, at all times relevant to this action, produced a generic form of metoclopramide. Mrs. Phelps was prescribed, and ingested, metoclopramide tablets from November 2002 to at least August 2009. Mrs. Phelps alleges that she developed a movement disorder called tardive dyskinesia during that time. Further, she alleges that her use of metoclopramide caused her to develop this disorder. Under the Federal Food, Drug, and Cosmetic Act (FDCA), a generic drug manufacturer's package inserts must match the package inserts of its name-brand counterpart. 21 U.S.C. § 301 et seq. During 2003 and 2004, Pliva's metoclopramide package inserts did not match the package inserts of its name-brand counterpart. Plaintiffs allege that Pliva's negligent failure to update its labeling injured Mrs. Phelps.

Pliva argues that plaintiffs' failure to update claim is preempted under Mensing and the FDCA, or alternatively, is not cognizable under Oregon law. Pliva also objects to Judge Coffin's findings regarding causation, Oregon's product liability presumption, and punitive damages.

III. DISCUSSION

A. *Mensing* Does Not Require Dismissal of Plaintiffs' Failure to Update Claim

Pliva argues that Judge Coffin has misconstrued the Supreme

Court's holding in PLIVA, Inc. v. Mensing. 131 S. Ct. 2567 (2011) and objects to the finding that plaintiffs' claim is not preempted. In his findings, Judge Coffin states that under Mensing, a generic manufacturer could not be liable for a failure to warn so long as it complied with the FDA regulations that require generic manufacturers to update its warnings to match those contained in the name-brand equivalents. (Doc. 344 at 2). Nonetheless, because Pliva allegedly failed to update its warnings in accordance with FDA regulations, Judge Coffin found that Pliva could be liable for that failure notwithstanding Mensing. Pliva argues that this interpretation inserts an exception into Mensing that is inconsistent with the Court's holding that any state-law failure to warn claim is preempted. (Doc. 347 at 8-9).

Under the FDCA, generic drug manufacturers "have an ongoing federal duty of 'sameness'" regarding their warning labels. Mensing, 131 S. Ct. at 2575. This duty of sameness requires that generic drug labeling match the equivalent name-brand drug's labeling. 21 U.S.C. § 355(j)(2)(A)(v). Furthermore, the FDCA prohibits generic manufacturers from issuing additional or different warnings on their products. Mensing, 131 S. Ct. at 2576. In light of these rules, the Supreme Court held that state-law failure to warn claims against generic manufacturers were preempted.

In Mensing, the plaintiffs argued that state law required

generic drug manufacturers to provide a stronger warning than the name-brand label, and that they failed to do so despite the known risk that metoclopramide can cause tardive dyskinesia. Id. at 2573. The Court explained that where it is impossible for a party to comply with both state and federal law, a conflict between the two exists, and state law must give way to federal law. Id. at 2577. Because it was impossible under the FDCA for the generic manufacturers to unilaterally strengthen their labels to conform to the state law requirements, the Court held that the plaintiffs' state-law failure to warn claims were preempted. Id. at 2577-78. (finding preemption because "[i]t was not lawful under federal law for the Manufacturers to do what state law required of them."). Pliva argues that the same rationale applies here because the Court did not exclude failure to update claims from its holding.

I conclude that Judge Coffin's interpretation of Mensing is consistent with that case and hold that plaintiffs' failure to update claim is not preempted under Mensing. While it is true that the Supreme Court in Mensing did not carve out an exception for failure to update claims, the absence of a specific exception does not warrant the conclusion that such claims are preempted under Mensing. This is especially true considering the factual differences between a failure to warn claim and plaintiffs' failure to update claim. The crux of the Court's decision in Mensing rested on the fact that the plaintiffs claimed that state law required

generic manufacturers to provide stronger labels than were permitted by federal law. As the Court pointed out, this was impossible for the generic manufacturers given the federal requirement that generic labels match name-brand labels. Id. at 2577-78. Plaintiffs' failure to update claim in this case, however, poses no such impossibility problem. Unlike the failure to warn claim in Mensing, plaintiffs do not claim that Pliva was required to use a different or stronger warning label; they merely claim that, under Oregon law, Pliva was negligent by failing to update its label to match the name-brand label - a requirement that is consistent with the FDCA. Thus, because plaintiffs' state-law claim does not make it impossible for Pliva to comply with federal law, no conflict exists and preemption is not warranted.[1]

Pliva nonetheless argues that the Supreme Court held that plaintiffs' failure to update claim was preempted in Mensing,

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[1]While Pliva cites a number of cases that have come to the opposite conclusion, I note that other courts have also found that Mensing is not so broad as to require preemption of failure to update claims. See E.g., Couick v. Wyeth, Inc., 2012 WL 79670 at *5 (W.D. N.C. Jan. 11, 2012) ("A state law claim for failure to include such warnings would not be preempted by federal law where the FDA would have permitted, or even required, such changes."); Cooper v. Wyeth, Inc., 2012 WL 733846 at *4 (M.D. La. Mar. 6, 2012) ("Since, as *Mensing* makes clear, the FDA's labeling regulations set the ceiling for labeling strength, any state law purporting to impose more stringent requirements would be preempted. However, a generic drug manufacturer's failure to adhere to the brand-name label the generic drug is tied to would plainly violate federal law and likely violate state law under the LPLA. In the latter scenario, the requirements of state law would coextend with, but would not exceed, the requirements of federal law, rendering impossibility preemption inapplicable.").

because the Court knew that at least one of the generic manufacturers in that case had failed to update its label, and yet the Court did not limit its holding to exclude those kinds of claims. Pliva claims that during the Mensing case, the Court was aware that Pliva may not have made the label change in 2003 and 2004 because Pliva's counsel wrote a letter to the Court's clerk mentioning that fact. (Doc. 347 at 9). According to Pliva, if the Supreme Court thought a failure to update claim was cognizable, it would have said so in Mensing.

I agree with Judge Coffin and conclude that Pliva's argument is inconsistent with Supreme Court precedent. The Supreme Court has a long-standing rule that if the Court has "never squarely addressed the issue . . . [the Court is] free to address the issue on the merits." Brecht v. Abrahamson, 507 U.S. 619, 631 (1993). Indeed, "[q]uestions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are not to be considered as having been so decided as to constitute precedents." Webster v. Fall, 266 U.S. 507, 511 (1925). Thus, an issue not "raised in briefs or argument nor discussed in the opinion of the Court. . . . is not a binding precedent on [that] point." U.S. v. L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 38 (1952).

Under this rule, Pliva's argument fails, and the precedential power of Supreme Court rulings demands such a result. Were it possible for a party to expand the scope of a Supreme Court ruling

by merely sending a letter, the Court's decisions could be subject to unwarranted, unconsidered expansion. Accordingly, because the Court in Mensing did not address the failure to update claim expressly in its decision, I refuse to find that it did so impliedly through its silence.

Nonetheless, Pliva argues that the Sixth and Eighth Circuits have held that plaintiffs' failure to update claim is preempted by Mensing. First, Pliva contends that in Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011), the Sixth Circuit's denial of a plaintiffs' petition for rehearing constituted a rejection of failure to update claims under Mensing because the plaintiffs raised the failure to update issue in their petition and the court nonetheless denied their petition. (Doc. 347 at 10-11). The Smith court's decision, however, did not mention anything about a failure to update claim, and referred only to the plaintiffs' failure to warn claim. Smith, 657 F.3d at 423 (holding that the plaintiffs' state-law failure to warn claims were preempted by Mensing because "[t]he Supreme Court held unequivocally . . . that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims").

Next, Pliva maintains that the Eighth Circuit's decision to deny supplemental briefing after the Supreme Court remanded the Mensing v. Wyeth case back to the court demonstrates that Mensing

preempts such claims. Mensing v. Wyeth, Inc., 2011 WL 4636653 (8th Cir. Sept. 29, 2011). Pliva reasons that because the Supreme Court remanded the case to the Eighth Circuit with instructions to conduct "further proceedings consistent with [the Court's] opinion", the Eighth Circuit's denial of supplemental briefing on the failure to update issue is evidence that Mensing did require preemption of failure to update claims. Mensing, 131 S. Ct. at 2582.

I reject these arguments for two reasons. First, neither court specifically addressed the failure to update theory in their decisions. Thus, while the issue may have lurked in the record, it was not decided by the court. Additionally, a court's decision to grant or deny rehearing or supplemental briefing does not necessarily indicate a substantive decision on issues proposed to be argued in that additional briefing or petition. Second, even assuming *arguendo* that the Sixth and Eighth Circuits did decide that failure to update claims are preempted, those circuits' decisions are not binding precedent on this court. Thus for the reasons stated above, I find that Judge Coffin did not err in concluding that plaintiffs' state-law failure to update claim is not preempted under Mensing, and I deny Pliva's motion for summary judgment on that issue.

B. Plaintiffs Assert a Viable Claim Under Oregon Law

Judge Coffin found that plaintiffs' failure to update claim is

viable under Oregon law. Pliva objects to this finding for two reasons. First, Pliva argues that plaintiffs' claim is really an attempt to enforce a violation of the FDCA, and the FDCA does not allow private enforcement. Second, Pliva argues that even if plaintiffs' claim is not preempted by the FDCA, Oregon law does not provide any cause of action for plaintiffs' claim because their claim is based on a federal, rather than a state duty.

1. The FDCA Does Not Preempt Independent State-Law Claims

In its objection, Pliva argues that plaintiffs' claim is preempted because under the FDCA only the federal government has the authority to enforce violations of the Act. See 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Thus, Pliva contends that the FDCA bars plaintiffs' claim because plaintiffs' claim is based on a violation of the FDCA. I recognized previously that Congress, in enacting the FDCA, explicitly stated that only the federal government can bring an action to enforce the provisions of the FDCA. (Doc. 296 at 17). For those reasons, I rejected plaintiffs' claims against Pliva for misbranding, failure to communicate drug safety information, and failure to test and monitor the effects of metoclopramide. (Doc. 296).

However, plaintiffs' failure to update claim cannot be dismissed as easily. As Judge Coffin explained, plaintiffs' claim

is not that Pliva violated the FDCA and thus should be liable for that violation. Rather, plaintiffs argue that Pliva was negligent when it failed to update its label. Under Oregon law, if a plaintiff establishes a manufacturer/user relationship, the manufacturer has a duty to exercise "due care to avoid foreseeable harm to the users of [its] product." Glover v. BIC Corp., 6 F.3d 1318, 1325 (1993) (quoting State ex rel. Western Seed Prod. Corp. v. Campbell, 250 Or. 262, 269, 442 P.2d 215 (1968) cert. denied, 393 U.S. 1093 (1969)). Plaintiffs maintain that Pliva breached this duty when it failed to update its label in accordance with the federal requirement. In other words, the duty under Oregon law to exercise due care is independent of the federal duty to update the label, though the federal duty to update can inform what the state-law duty of due care requires.

In fact, the Supreme Court has distinguished between a private cause of action that seeks only to enforce a violation of the FDCA, and a private cause of action based on a traditional category of state law that parallels the requirements of the FDCA. Compare Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2000) with Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996); see also Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013).

In Medtronic v. Lohr, the plaintiffs sued the manufacturer of a pacemaker under state law negligence theories, including a failure to warn claim. Medtronic, 518 U.S. at 481. Under § 360k of

the Medical Device Amendment (MDA) of the FDCA, an explicit preemption clause prohibits states from creating or continuing any requirement relating to medical devices which imposes different or additional requirements than those contained in the MDA. Id. at 482 (citing 21 U.S.C. § 360k(a)). The defendant argued that § 360k therefore preempted any and all state law claims against a medical device manufacturer. Id. at 486. The Supreme Court rejected this argument, however, and held that the express preemption section of the MDA does not prohibit a state from providing traditional damages remedies for violation of common law duties when the state law duties parallel federal requirements. Id. at 495. The Court explained that under the defendant's interpretation of the statute:

> Congress effectively [would preclude] state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use," 90 Stat. 539 (preamble to Act).

Id. at 487.

In Buckman Co. v. Plaintiffs' Legal Comm., the plaintiffs brought a state tort law claim against a bone screw manufacturer's consulting company for its allegedly fraudulent misrepresentations

to the FDA. Buckman, 531 U.S. at 343. The Supreme Court held that state law fraud-on-the-FDA claims are impliedly preemepted because they conflict with federal law. Id. at 348. The Court explained that policing fraud against federal agencies is not an area in which states traditionally occupy. Id. at 347. The Court further pointed out that the regulatory relationship between a federal agency and the entities it regulates is wholly federal in character, as it is created by, governed by, and terminated by federal law. Id. at 347. From this, the Court concluded that a state law claim based solely on the violation of the approval process - which exists only by virtue of the FDCA - is preempted. Id. at 352-53.

Importantly, the Court distinguished fraud-on-the-agency claims from the claims in Medtronic. The Court explained that the claim was preempted because it "exist[ed] solely by virtue of the FDCA disclosure requirements" but that it was "clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, *not solely from the violation of FDCA requirements*." Id. (emphasis added). The Court clarified that "although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." Id. at 353.

Judge Coffin found that this case is similar to Medtronic, because plaintiffs' claim is not based solely on a violation of the FDCA. Rather, Judge Coffin found that the plaintiffs' failure to update claim, while informed by the FDCA, is based in state tort law.

Pliva argues, however, that plaintiffs' failure to update claim is not independent from the FDCA because Oregon law does not require a generic drug manufacturer to match its labeling to that of the brand name drug manufacturer.[2] This argument is not persuasive. Under Buckman, the Supreme Court emphasized that preemption was warranted in that case because the fraud-on-the-agency claim existed *solely* by virtue of the FDCA; other claims could survive preemption if the federal law is not a critical element in the claim and the claim is based on "traditional state

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[2]Pliva filed a Notice of Supplemental Authority in Support of Objections (doc. 348) citing to recent decisions in the District Court of Minnesota which dismissed two plaintiffs' state-law failure to update claims against the defendants. Abicht v. PLIVA, Inc., No. 12-1278 (PAM/JJG) (D. Minn. Jan. 9, 2013) and White v. PLIVA, Inc., No. 12-2172 (PAM/JJG) (D. Minn. Jan. 9, 2013). In those cases, the District Court rejected Pliva's argument that Mensing preempted the plaintiffs' failure to update claim, recognizing that "Plaintiffs also raise a different claim, one that Mensing did not address: are claims that a generic drug failed to include warnings that the brand-name drug's label contained cognizable under state law?" (Doc. 348-1 at 4). In answering that question, the court determined that the FDCA preempted such a state-law claim because the FDCA precludes private enforcement of the act. Id. at 5. However, I disagree and find that plaintiffs employ the FDCA to inform the standard of care owed under Oregon law; plaintiffs are not "enforcing" the FDCA.

tort law which had predated the federal enactments." Buckman, 531 U.S. at 353. In this case, plaintiffs argue that Pliva's failure to update its labels was a breach of its Oregon law duty to exercise due care to avoid foreseeable harm to the users of its product. Here, the plaintiffs do not seek to enforce or restrain violations of the FDCA, but rather seek damages under Oregon negligence law. The fact that Oregon's product liability law does not specifically mirror the FDCA requirements is not fatal to plaintiffs' claim.

Pliva's argument was recently addressed and rejected by the Ninth Circuit in Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013). In that case, the plaintiffs sued a medical device company under a theory of state-law negligence. Id. at 1226. Specifically, the plaintiffs claimed that the manufacturer had violated Arizona's state-law duty of care by failing to report known risks associated with the use of its device to the FDA; the MDA required manufacturers to report such risks to the FDA. Id. The Ninth Circuit concluded that the plaintiffs' state-law failure to warn claim was not preempted because the claim is "independent of the FDA's pre-market approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*." Id. at 1233. In a concurring opinion, Judge Watford rejected the defendant's argument that the plaintiff's claim "seeks to enforce an exclusively federal requirement and is not based on traditional state tort law because

Arizona law has never required adverse events to be reported to the FDA." Id. at 1235. Judge Watford explained:

> [A]ccepting that argument would require an unwarranted expansion of *Buckman*'s rationale. Central to the Court's reasoning in *Buckman* was that the state law claim asserted there "exist[ed] *solely* by virtue" of the federal enactments, because state law traditionally had no role to play in policing "the relationship between a federal agency and the entity it regulates." But *Buckman* left intact claims "relying on traditional state tort law which had predated the federal enactments" in question.

Id. (citations omitted) (emphasis in original). Thus, the mere fact that Oregon law does not specifically require a generic manufacturer to match its label does not bar plaintiffs' state-law negligence claim.

I agree with Judge Coffin's finding that plaintiffs' failure to update claim is distinguishable from the claim in Buckman, and therefore is not preempted by the FDCA. I further hold that Judge Coffin's findings on this issue are consistent with the Ninth Circuit's recent decision in Stengel. Thus, I adopt Judge Coffin's recommendation and deny Pliva's motion for summary judgment on that issue.

2. Plaintiffs' Claim Has a Basis In Oregon Law

Next, Pliva objects to Judge Coffin's finding that plaintiffs state a viable Oregon law claim. Pliva argues that plaintiffs' claim is not based in Oregon law, because there is no Oregon law that imposes a duty on a generic drug manufacturer to match its label to that of the name-brand manufacturer.

Pliva's argument is misplaced. As explained above, plaintiffs' claim is not that Pliva violated the FDCA, but rather that Pliva was negligent under Oregon law for failing to update its label. As Judge Coffin explained, Oregon law does recognize such a claim. Under Or. Rev. Stat. § 30.900, a product liability civil action is defined as a "civil action brought against a manufacturer . . . of a product for damages for personal injury, death or property damage arising out of: . . .(2) Any failure to warn regarding a product; or (3) Any failure to properly instruct in the use of a product." Or. Rev. Stat. § 30.900. Oregon's product liability statute "embraces all theories a plaintiff can claim in an action based on a product defect," including claims based on theories of negligence. Kambury v. Daimler Chrysler Corp., 185 Or. App. 635, 639, 60 P.3d 1103 (2008); Simonsen v. Ford Motor Co., 196 Or. App. 460, 466, 102 P.3d 710 (2005).

While Oregon law does not specifically impose a duty of sameness on generic drug manufacturers, the federal duty to do so can be used to inform Oregon's standard of care. Cf. Shahtout By and Through Shahtout v. Emco Garbage Co., Inc., 298 Or. 598, 601, 695 P.2d 897 (1985) (holding that even where a statute or regulation does not provide a person injured by its violation with a private cause of action for damages, the violation of the statute can be relevant to a plaintiff's common law negligence claim). Thus, because plaintiffs' negligence claim alleges that they

suffered personal injury arising out of Pliva's failure to update its labels, their claim is encompassed by § 30.900.

In sum, for the foregoing reasons, I adopt Judge Coffin's finding that plaintiffs have a valid state-law claim, and therefore deny Pliva's motion for summary judgment on that issue.

C. Genuine Issues of Material Fact Exist Concerning Proximate Cause

Next, Pliva objects to Judge Coffin's proximate cause findings. In his F&R, Judge Coffin rejected Pliva's argument that plaintiffs could not prove proximate cause because neither Mrs. Phelps nor her doctors read the metoclopramide label. In rejecting this argument, Judge Coffin found that under Oregon law, the sufficiency of a warning is an expert and jury question. Judge Coffin concluded that a reasonable juror could find that, had Pliva's package insert included the warning that was on the name-brand packages, Mrs. Phelps or her doctors would have noticed, read, and heeded that warning. Thus, Judge Coffin found that a reasonable juror could find that Pliva's failure to use that warning was the proximate cause of Mrs. Phelps' injuries.

Pliva argues that plaintiffs have not and cannot prove that the lack of a warning on its packages was a substantial cause of Mrs. Phelps' injuries. According to Pliva, without proof that either Mrs. Phelps or her doctors read or relied on the package inserts, the lack of a warning in those inserts could not have caused her injuries. Pliva also objects to Judge Coffin's

discussion of sufficiency of warning in terms of causation. Pliva argues that "There is no explanation how one relates to the other. In fact, they do not. Any issue regarding the 'sufficiency of the warnings' is separate from and not relevant to the proximate cause issue." (Doc. 347 at 27).

I reject these arguments as inconsistent with Oregon law. Under Oregon law, evidence is sufficient to prove causation if a jury could draw an inference that a warning would have been generally effective in preventing the injury. Baccelleri v. Hyster, Co., 287 Or. 3, 597 P.2d 351 (1979). Thus, Pliva's argument that the sufficiency of a warning is irrelevant to proximate cause is incorrect. For example, in Baccelleri, the plaintiff brought a products liability action against the manufacturer of a forklift truck after a forklift backed over his legs. Id. at 5, 597 P.2d 351. The plaintiff claimed that the forklift was "unreasonably dangerous and defective because it lacked both visual and audible warning alarms to alert persons that the machine was backing." Id. The Oregon Supreme Court rejected the defendant's argument that there was no evidence that the absence of a back-up alarm caused the plaintiff's injuries:

> It is true there is no testimony that this accident would not have happened if an alarm had been provided, but there seldom is such evidence in a case in which the charge is failure to warn. It is sufficient to prove causation if there is evidence or the jury can draw an inference that a warning is generally effective in preventing such accidents.

Id. at 7, 597 P.2d 351.

Additionally, Oregon courts have found that a failure to read a label does not preclude a plaintiff from proving causation. In Benjamin v. Wal-Mart Stores, Inc., the Oregon Court of Appeals concluded that, despite lack of evidence that the decedent read the warning, "there was ample evidence from which the jury could have found that the inadequate warning on the . . . heater was a substantial factor in causing [the decedent's] death." 185 Or. App. 444, 459-60, 61 P.3d 257 (2002). Despite the factual distinctions between these cases and the case at bar, the causation principle remains the same.

Indeed, this court has also recently declined to find that the failure to read a warning label by a doctor precludes a finding of proximate cause where there is evidence that the doctor would have acted differently had she been warned. For example, in Schoenborn v. Stryker Corp., the manufacturer of a pain pump argued that the plaintiff could not prove that any alleged failure to warn by the manufacturer caused the plaintiff's injury. 801 F. Supp. 2d 1098, 1102 (2011). The manufacturer's argument was based on the fact that the doctor admitted that she did not read the instructions for use prior to implanting the pain pump. Id. This court concluded that a genuine issue of material fact remained as to whether the failure to warn caused the plaintiff's injuries, because the doctor had stated that she would have implanted the pain pump differently had

she known that the FDA had not approved them for that use. Id.

Thus, the fact that neither Mrs. Phelps nor her doctors read or relied on Pliva's package inserts is not determinative of proximate cause. As in Schoenborn, the doctors who prescribed metoclompramide to Mrs. Phelps have testified that at the time they prescribed metoclopramide they did not know of the dangers associated with using metoclopramine for longer than 12 weeks. (Doc. 308 at ¶¶ 7-10, 12, 14). Additionally, the doctors testified that had they known of that danger, they would not have prescribed metoclopramide to Mrs. Phelps. Id. In a motion for summary judgment the court must construe all inferences in favor of the plaintiffs. In so doing, I find that a genuine issue of material fact remains as to whether Pliva's alleged failure to update its label was a proximate cause of Mrs. Phelps' injuries.

D. Plaintiffs Submit Sufficient Evidence Regarding General and Specific Causation

Next, Pliva objects to Judge Coffin's finding that plaintiffs put forth evidence sufficient to survive summary judgment on the issues of general and specific causation. After reviewing the record, I agree with Judge Coffin's findings.

Under Oregon law, when the element of causation involves a complex medical question, a plaintiff must present expert testimony that there is a reasonable medical probability of causation. Chouinard v. Health Ventures, 179 Or. App. 507, 512, 39 P.3d 951 (2002). Therefore, a plaintiff must present expert testimony to

prove not only general causation (i.e. that the defendant's product could cause the injury), but also to prove specific causation (i.e. that there is a reasonable probability that defendant's product caused the plaintiff's particular injury). "Proof of cause-in-fact 'must have the quality of reasonable probability, and a mere possibility that the alleged negligence of the defendant was the . . . cause of plaintiff's injuries is not sufficient." Joshi v. Providence Health Sys. of Or. Corp., 198 Or. App. 535, 545, 108 P.3d 1195 (2005).

Oregon courts have recognized that in these cases, there is a significant difference between establishing an injury and establishing its cause. Chouinard, 179 Or. App. at 513, 39 P.3d 95 (citing Howerton v. Pfaff, 246 Or. 341, 347, 425 P.2d 533 (1967)). Thus, expert testimony which states only that the defendant's negligence is a possible cause of the injury will not be sufficient to send the claim to a jury. The purpose of the requirement for a showing of "reasonable medical probability" of causation in cases involving complex medical questions is to prevent "jurors from speculating about causation in cases where that determination requires expertise beyond the knowledge and experience of an ordinary lay person." Baughman v. Pina, 200 Or. App. 15, 18, 113 P.3d 459 (2005) (citing Howerton, 246 Or. at 347-48, 425 P.2d 533).

Here, neither of the parties disputes that causation in this case involves a complex medical question. Further, Pliva does not

dispute that Mrs. Phelps' doctors are qualified to render opinions on causation in this case. Thus the issue is whether the experts in this case have testified that causation was probable or merely possible.

First, I find that plaintiffs have provided expert testimony that Pliva's product, metoclopramide, is a probable cause of tardive dyskinesia. Pliva argues that "[t]he state of the evidence is that none of the physicians addressed [the] general causation issue." (Doc. 347 at 29). This contention, however, is not supported by the record. At least two of Mrs. Phelps' doctors testified about the causal connection between metoclopramide and the development of tardive dyskinesia. For example, Dr. Lockfeld, Mrs. Phelps' neurologist, was asked in his deposition: "Is metoclopramide associated with tardive dyskinesia?" and "Is it a known cause of tardive dyskinesia?" To both questions, Dr. Lockfeld answered "Yes." (Doc. 310-6 at 31). Additionally, Dr. Peterson testified in her deposition that it "seems like it's fairly common" for metoclopramide to cause tardive dyskinesia." (Doc. 310-7 at 25).

Oregon courts have made it clear that "magic words" are not required to find that an expert has testified to a reasonable medical probability of causation, so long as the expert's opinion in its entirety establishes a probability of causation. Hudjohn v. S&G Mach. Co., 200 Or. App. 340, 353, 114 P.3d 1141 (2005) (holding

that expert's testimony that the "inhalation of toxins **may be** accounting for **some degree** of this impairment" failed to state reasonable probability of causation because it was stated in terms of possibility, not probability) (emphasis in original). In this case, the doctors' testimony about whether metoclopramide can cause tardive dyskinesia is not framed in terms of possibility, but rather speaks in terms of certainty and probability. Thus, because the expert testimony establishes that there is a reasonable medical probability that Pliva's product causes tardive dyskinesia, plaintiffs have presented evidence of general causation.

Second, I find that plaintiffs have put forth expert testimony that there is a reasonable medical probability that Mrs. Phelps' use of Pliva's product caused her tardive dyskinesia. Pliva contends that none of Mrs. Phelps' physicians opined that metoclopramide was the probable cause of her tardive dyskinesia or diagnosed her with "metoclopramide-induced tardive dyskinesia." (Doc. 347 at 29). Again, these arguments are not supported by the record. Both Drs. Lockfeld and Peterson testified that there is a reasonable medical probability that metoclopramide caused Mrs. Phelps' tardive dyskinesia. For example, Dr. Lockfeld testified as follows:

> Q: In your medical opinion does Mrs. Phelps have tardive dyskinesia?
>
> A: Yes. . . She did have tardive dyskinesia at the time when I was seeing her.

> Q. And at that time was it your opinion that her tardive dyskinesia was caused by metoclopramide?
>
> A. That was my opinion, yes.
>
> Q. And has anything occurred since then to change your opinion?
>
> A. No.

(Doc. 310-6 at 35). Clearly Dr. Lockfeld had not only diagnosed her with tardive dyskinesia, but believed that her tardive dyskinesia was caused by metoclopramide.

Additionally, Dr. Peterson testified she diagnosed Mrs. Phelps with tardive dyskinesia, and that Mrs. Phelps' tardive dyskinesia symptoms were "most likely" related to her use of metoclopramide. (Doc. 310-7 at 11). Again, Dr. Peterson did not testify that there is a mere possibility that Mrs. Phelps' use of metoclopramide was a cause of her tardive dyskinesia, but rather that her dyskinesia was "most likely" related her use of metoclopramide. Thus, I find that plaintiffs have provided evidence that there is a reasonable medical probability that Mrs. Phelps' use of Pliva's product caused her injury. Therefore, I adopt Judge Coffin's findings and deny summary judgment on the issues of general and specific causation.

E. Plaintiffs Have Rebutted the Presumption Under Or. Rev. Stat. § 30.910 That the Product Was Not Unreasonably Dangerous

Judge Coffin found that plaintiffs have presented evidence to rebut the presumption in Oregon law that products are not unreasonably dangerous. Pliva objects to this finding, and claims that it is not supported by the record.

Under Oregon's product liability statute, a plaintiff must establish not only that there was a failure to warn or failure to properly instruct, but also that doing so rendered the product unreasonably dangerous. Russell v. Deere & Co., 186 Or. App. 78, 83, 61 P.3d 955 (2003). Usually, the question of whether a product is unreasonably dangerous is a jury question. McCathern v. Toyota Motor Corp., 332 Or. 59, 77, 23 P.3d 320 (2001). However, the Oregon legislature created a rebuttable presumption that "a product as manufactured and sold or leased is not unreasonably dangerous for its intended use." Or. Rev. Stat. § 30.910. This requirement reinforces the common law principle that the mere existence of a defect in a product does not necessarily render it unreasonably dangerous. Russell, 186 Or. App. at 83, 61 P.3d 955. Therefore, under Oregon law, a plaintiff claiming products liability, "must affirmatively put forth some evidence on the issue of dangerousness before the issue may properly be submitted to a jury." Id. Thus, § 30.910 does not permit a plaintiff to "rely on the bare assertion of a defect from which a jury may infer unreasonable dangerousness . . . ." Id.

After reviewing the record, I agree with Judge Coffin that plaintiffs have affirmatively put forth some evidence that Pliva's product was unreasonably dangerous for its intended use. Pliva maintains that Mrs. Phelps' use of metoclopramide for more than 12 weeks was an "off-label" use. In 2004, the warning labels on the

name-brand version of metoclopramide, were changed to include a specific warning against using the drug for more than 12 weeks: "**Therapy Should Not Exceed 12 Weeks in Duration.**" Plaintiffs present evidence, however, that Pliva failed to update its label to match the new warning. Thus, Mrs. Phelps' use of Pliva's product for more than 12 weeks during the time that Pliva's label was not updated cannot be considered an "off-label" use, as the label provided on Pliva's product did not describe such a limitation on use.

Pliva nonetheless argues that Dr. Phuntshog testified that his prescription of metoclopramide in 2004 for longer than 12 weeks was an "off-label" use. (Doc. 347 at 30). However, that testimony was elicited from Dr. Phuntshog after showing him the 2004 name-brand label that had not been provided in Pliva's package inserts. Thus, whether Dr. Phuntshog, after reading a label that was never provided, concluded that using the product for more than 12 weeks was an "off-label use" is irrelevant, as that label was never provided to Mrs. Phelps or her doctors.

Pliva also contends that even the pre-2004 name-brand label (to which it had conformed) made the use of metoclopramide for more than 12 weeks an "off-label" use. I disagree. The record indicates that the 2002 name-brand label included only an indication that the drug was a short-term therapy, but did not include any express time

limitation.[3] Thus, the label was strengthened in 2004 to include a limitation on use that was not previously there. Additionally, plaintiffs have put forth evidence that prolonged use of metoclopramide can cause injury to users.

Accordingly, I find that the plaintiffs have presented some evidence that the 2003/2004 Pliva label rendered the product unreasonably dangerous for its intended use, and therefore have rebutted the presumption in § 30.910. For that reason, I adopt Judge Coffin's findings and deny Pliva's motion for summary judgment on that issue.[4]

F. Pliva's Argument That Plaintiffs Claim Pliva Had a Duty to Provide an Inadequate Warning Fails

Pliva next argues that plaintiffs' state law claim must fail because there is no duty under Oregon law to provide an "inadequate" warning. Pliva contends that plaintiffs have alleged

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[3]The 2002 labels read "Reglan tablets are indicated as short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy."

[4]Pliva also argues that Judge Coffin supported his conclusion on this issue by citing to portions of plaintiffs' statement of facts that cite to exhibits which had been stricken by Judge Coffin. (Doc. 347 at 31 n. 9). After reviewing Judge Coffin's order (doc. 339), I find that Judge Coffin's did not rely on evidence stricken from the record when citing to paragraphs 60-63 of plaintiffs' statement of facts. (Docs. 344 at 13 and 308). In his opinion and order on Pliva's motion to strike, Judge Coffin granted the motion to strike the *additional* deposition testimony and new materials from other cases, but did not strike the original exhibits filed by plaintiffs. (Doc. 339 at 8).

in their amended complaint that all pre-2009 metoclopramide labels were inadequate, including the name-brand labels. Thus, according to Pliva, because Oregon law does not impose a duty on manufacturers to provide an "inadequate" warning, its failure to update its label to match an "inadequate" label cannot form a basis for liability under Oregon law.[5]

Judge Coffin rejected this argument and found that because there is evidence that Pliva failed to update its label, a reasonable jury could find that it was negligent in failing to do so. Pliva objects to Judge Coffin's finding, and argues that because there is no duty to provide an inadequate warning, no reasonable jury could find that it breached that standard of care.

I reject this argument, and adopt Judge Coffin's findings on this issue. Instructive here is the plaintiffs' actual claim. Plaintiffs claim that Pliva was negligent in failing to update its product labels. As described above, Oregon law requires a manufacturer to exercise due care towards the purchasers of its products. Thus, the standard of care which the jury would assess is not whether Pliva provided an adequate warning, but rather whether Pliva exercised due care. Thus, regardless of the fact that Oregon law does not impose a duty to provide an inadequate warning, Pliva was still under a duty to exercise due care, and a jury could find

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[5]Plaintiffs object to this reading of their amended complaint, and argue that their complaint does not make that claim. (Doc. 349 at 15-16).

that it breached that duty when it failed to update its label. Thus, I adopt Judge Coffin's findings and deny summary judgment on that issue.

G. Plaintiffs' Present Sufficient Evidence to Support a Punitive Damages Claim

Finally, Pliva objects to Judge Coffin's finding that there is sufficient evidence on the issue of punitive damages. In his findings, Judge Coffin rejected Pliva's argument that it could not be liable for punitive damages under Or. Rev. Stat. § 30.927 because its label was approved by the FDA after finding sufficient evidence that Pliva's label was not labeled in accordance with the approval of the FDA in 2003 and 2004. In its objections, Pliva makes two arguments: (1) that its package inserts were at all times "approved" by the FDA; and (2) that plaintiffs have provided no evidence of malice, recklessness or outrageous indifference on the part of Pliva. For the reasons stated below, I reject these arguments and adopt Judge Coffin's findings.

Under § 30.927, punitive damages against drug manufacturers are allowed only in two instances. In this case, the relevant instance is where the drug is not "manufactured and labeled in relevant and material aspects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the Federal Food, Drug and Cosmetic Act; . . ." Or. Rev. Stat. § 30.927(1)(a). In addition to proving that the drugs were not labeled according to FDA approval, the plaintiff

must also prove

> by clear and convincing evidence that the party against whom punitive damages are sought has acted with malice or has shown a reckless and outrageous indifference to a highly unreasonable risk of harm and has acted with a conscious indifference to the health, safety and welfare of others.

Id. § 31.730(1).

First, I reject Pliva's argument that its label was at all times approved by the FDA. Pliva contends that in 2003 and 2004 the label on its product was "approved" because the FDA at some time had indeed approved those labels. However, this argument ignores the fact that under the FDCA, a generic manufacturer's label must match the label of its brand-name equivalent at all times. Mensing, 131 S. Ct. at 2575 (stating that generic manufacturers "have an ongoing federal duty of 'sameness'" regarding their warning labels). Pliva has not disputed that its label during 2003 and 2004 did not match the brand-name label as required by the FDCA. The FDCA regulatory scheme is such that the label that is currently approved for the brand-name product is the "approved" labeling for the generic product. See e.g. 21 U.S.C. § 355 (j)(2)(A)(v). When the brand-name product changes its label, and that label is approved by the FDA, the generic manufacturer has an "ongoing" duty to ensure its label matches. Mensing, 131 S. Ct. at 2575. I decline to read the term "an approval" so broadly as to swallow up the FDCA sameness requirement.

Second, I find that plaintiffs have presented sufficient

evidence under § 31.730(1) to survive summary judgment on that issue. Pliva argues that plaintiffs have failed to produce any evidence that would satisfy the clear and convincing evidentiary requirement under § 31.730(1). Pliva supports this argument by relying on a declaration by its own representative that (1) the FDA notifies generic manufacturers when they need to update their package inserts, (2) Pliva followed those procedures, and (3) that Pliva did not receive any FDA notifications that they needed to update the package inserts. (Doc. 347 at 34).

However, these declarations do not disprove that Pliva may have acted recklessly or outrageously indifferent to a highly unreasonable risk of harm. In 2000, the FDA changed its reporting practices and alerted generic manufacturers through a policy release that, while "[p]reviously, OGD notified the appropriate ANDA sponsors when the approved labeling of their RLD changed . . . "[t]he sponsor of an ANDA is now responsible for ensuring that the labeling contained in its application is *the same as* the currently approved labeling of the RLD."[6] Thus, the fact that Pliva did not receive a FDA notice requiring it to update its label does not preclude a finding that they acted with malice or reckless and outrageous indifference, because the FDA no longer sends such

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[6]Guidance for Industry "Revising ANDA Labeling Following Revision of the RLD Labeling" (2000) available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072891.pdf (emphasis in original).

notices. Indeed, Pliva's contention that it had no responsibility to update its label, without a notice from the FDA, itself is evidence that could suggest that they acted with recklessness and outrageous indifference particularly when there is evidence that Pliva's label did not match the brand-name label as required by the FDCA.

In a motion for summary judgment, all inferences must be drawn in favor of the non-moving parties. Drawing such inferences, I conclude that there is a genuine issue of material fact as to whether Pliva "acted with malice or has shown a reckless and outrageous indifference to a highly unreasonable risk of harm and has acted with a conscious indifference to the health, safety and welfare of others." Whether or not plaintiffs will ultimately prove that by clear and convincing evidence is a question for the jury.

IV. CONCLUSION

For the foregoing reasons, Judge Coffin's Findings and Recommendation issued on December 19, 2012 (doc. 344) is ADOPTED. Defendant Pliva's motion for summary judgment (doc. 301) is DENIED.

IT IS SO ORDERED.

DATED this 2nd day of ~~March~~ April, 2013.

Ann Aiken
United States District Judge